

510k Summary	CLARITY MEDICAL SYSTEMS, INC.
	DATE: JANUARY 26, 2009

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

Device Name: RetCam Portable Ophthalmic Imaging System

Common Name(s): Ophthalmic Imaging System

K083771

Classification Name(s): Ophthalmic Camera

Manufacturer: Clarity Medical Systems, Inc.

Reg. Number: 2952489

Address: 5775 West Las Positas Boulevard
Pleasanton, CA 94588-4084
(925) 463-7984

Classification(s):

Device Class: Class II

Classification Panel: Ophthalmology

Product Code(s): HKI

Equivalent Predicate Device: RetCam Shuttle Ophthalmic Imaging System, K081858

Device Description:

The RetCam Portable Imaging System is designed to quickly and easily capture wide field, digital images and videos of the eye. The optional hard side or soft side packaging allows for easy transport from one location to another within or outside the hospital or clinic. The reduced packaging dimensions enhance the ease of use in confined space situations.

Indication for Use:

The RetCam Portable Ophthalmic Imaging System is indicated for general ophthalmic imaging including retinal, corneal and external imaging.

Company Contact:

Gary A. Seeger

Vice President, Quality Assurance and Regulatory Affairs
Clarity Medical Systems, Inc.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 2009

Clarity Medical Systems, Inc
c/o Gary A. Seeger
5775 W. Las Positas Blvd.
Pleasanton, CA 94588

Re: K083771

Trade/Device Name: RetCam Portable Ophthalmic Imaging System
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: Class II
Product Code: HKI
Dated: December 15, 2008
Received: December 18, 2008

Dear Mr. Seeger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose
and Throat Devices

Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number:

Device Name(s): RetCam Portable Ophthalmic Imaging System

Indications for Use Statement(s) for each and all above listed RetCam Systems:

The RetCam Portable Ophthalmic Imaging System is indicated for general ophthalmic imaging including retinal, corneal and external imaging.

Prescription Use X

OR

Over-The-Counter Use _____

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)


(Division Sign-Off)
Division of Ophthalmic and Ear,
Nose and Throat Devices

510(k) Number K083771